
UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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|--------------------------|---|----------------------------------|
| UNITED STATES OF AMERICA | : | Hon. Joseph A. Dickson |
| | : | |
| v. | : | Mag. No. 18-6542 |
| | : | |
| WILLIAM OTTOMBRINO | : | <u>CRIMINAL COMPLAINT</u> |
| | : | |

I, Kurtis Roinestad, being duly sworn, state the following is true and correct to the best of my knowledge and belief:

SEE ATTACHMENT A

I further state that I am a Special Agent of the Food and Drug Administration, Office of Criminal Investigations, and that this complaint is based on the following facts:

SEE ATTACHMENT B


continued on the attached pages and made a part hereof.



Kurtis Roinestad, Special Agent
Food and Drug Administration
Office of Criminal Investigations

Sworn to before me, and
subscribed in my presence

March 13, 2018 at
Newark, New Jersey


HONORABLE JOSEPH A. DICKSON
UNITED STATES MAGISTRATE JUDGE

ATTACHMENT A

COUNT ONE

[Receipt and Delivery of Misbranded Drugs in Interstate Commerce]

From in or about December 2016 through in or about March 2018, in Middlesex County in the District of New Jersey, and elsewhere, defendant

WILLIAM OTTOMBRINO

did with the intent to defraud or mislead, receive and cause the receipt in interstate commerce, of misbranded drugs namely, sildenafil, in that the label was false and misleading, and deliver and cause to be delivered, and proffer delivery of them for pay or otherwise.

In violation of Title 21, United States Code, Sections 331(c) and 333(a)(2), and Title 18, United States Code, Section 2.

COUNT TWO

[Trafficking in Counterfeit Goods]

From in or about December 2016 through in or about March 2018, in Middlesex County in the District of New Jersey, and elsewhere, defendant

WILLIAM OTTOMBRINO

did knowingly and intentionally traffic in goods using a counterfeit mark on or in connection with such goods, namely "Extenze Maximum Strength Male Enhancement Nutritional Supplement," which counterfeit marks were identical with and substantially indistinguishable from the genuine mark in use and registered for that good on the principle register in the United States Patent and Trademark Office, and the use of which marks was likely to cause confusion, mistake and deception regarding said mark.

In violation of Title 18, United States Code, Section 2320, and Title 18, United States Code, Section 2.

ATTACHMENT B

I, Kurtis Roinestad, am a Special Agent with the Food and Drug Administration Office of Criminal Investigations ("FDA/OCI"). I have been employed as a Special Agent with the FDA/OCI since 2008. I am currently assigned to the New York Field Office in Jersey City, New Jersey. Prior to joining the FDA/OCI, I was a U.S. Postal Inspector from 2003 to 2008, assigned to the Securities and Commodities Fraud Task Force. I am a graduate of the U.S. Postal Inspector Basic Training Academy in Potomac, Maryland, as well as the Federal Law Enforcement Training Center in Glynco, Georgia. As a Special Agent with the FDA/OCI, I am responsible for conducting investigations involving criminal violations of the Federal Food, Drug and Cosmetic Act (the "FDCA"), codified as Title 21, United States Code, § 301 et seq., and related provisions in Title 18. During the past ten (10) years with the FDA/OCI, I have become familiar with the federal statutes enforced and the industry regulated by the FDA. I have also investigated and become familiar with the distribution of unapproved drugs, prescription drug diversion schemes, legitimate methods of marketing and packaging of prescription drugs, and the manner in which individuals circumvent legitimate channels of distribution to obtain and distribute prescription drugs fraudulently. I have participated in this investigation, discussed this matter with other law enforcement officers, and have reviewed documents and other materials. I have knowledge of the following facts. Because this Criminal Complaint is being submitted only for the limited purpose of establishing probable cause, I have not included each and every fact known to me concerning this investigation. I have set forth only the facts which I believe are necessary to establish probable cause. Unless specifically indicated, all conversations and statements described in this affidavit are related in substance and in part and all dates and figures are approximate.

1. At all times relevant to this Complaint:

- a. Defendant WILLIAM OTTOMBRINO ("OTTOMBRINO") was a resident of Freehold, New Jersey.
- b. PRICE RITE SHOPPING GROUP LLC ("PRICE RITE") was an entity operated by defendant OTTOMBRINO through which he sold, among other things, misbranded drugs.
- c. Socialite E-Cigs LLC ("SOCIALITE") was a business operated by defendant OTTOMBRINO, which included several tobacco and e-cigarette

storefronts in various locations in New Jersey, including locations in East Brunswick, Freehold and Toms River.

d. Victim Company is a North American company headquartered in Monrovia, California, that manufactures and distributes, among other things, Extenze® (“Extenze”), an herbal nutritional supplement that purports to promote “natural male enhancement.” Victim Company registered trademarks for Extenze on the principal register in the United States Patent and Trademark Office (“USPTO”), and these trademarks were in use.

The United States Food and Drug Administration, Definitions and Regulations

2. The United States Food and Drug Administration (“FDA”) was the federal agency within the executive branch responsible for protecting the health and safety of the American public by enforcing the Federal Food, Drug, and Cosmetic Act (“FDCA”). Among the purposes of the FDCA was to assure that drugs sold for human use were safe, effective, and bore accurate labeling containing all required information. The FDA’s responsibilities under the FDCA included regulating the manufacture, labeling, and distribution of all drugs shipped or received in interstate commerce.

3. Under the FDCA, drugs were defined as, among other things, articles intended for use in the cure, mitigation, treatment or prevention of disease in humans (21 U.S.C. § 321(g)(1)(B)); articles intended to affect the structure or function of the body of humans (21 U.S.C. § 321(g)(1)(C)); or articles intended for use as components of other drugs (21 U.S.C. § 321(g)(1)(D)).

4. The FDCA defines “interstate commerce” as “commerce between a State or Territory and anyplace outside thereof.” (21 U.S.C. § 321(b)).

5. The FDCA prohibited, among other things, the act of receiving a misbranded drug in interstate commerce and delivering or proffering such drug for pay or otherwise, as well as causing such an act. (21 U.S.C. § 331(c)).

6. Under the FDCA, a drug was misbranded if, among other things, its labeling was false or misleading in any particular manner (21 U.S.C. § 352(a)) or if its labeling did not bear the established name, quantity and proportion of each active ingredient (21 U.S.C. § 352(e)(1)(A)(2)).

7. Under the FDCA, the term “label” means a display of written, printed, or graphic matter upon the immediate container of any article. 21 U.S.C. § 321(k). The term “labeling” includes all labels, as well as other printed

or graphic matter upon any article or any of its containers or wrappers, or accompanying such article. 21 U.S.C. § 321(m).

The Scheme to Receive and Deliver Misbranded Drugs In Interstate Commerce

8. Sildenafil was the active ingredient in the FDA-approved erectile dysfunction (“ED”) drug marketed as Viagra®. Sildenafil is a “drug” within the meaning of the FDCA.

9. A cooperating witness (“CW”)¹ advised law enforcement that CW was engaged in the sale of dietary supplements and natural male sexual enhancement pills through an online business. CW further informed law enforcement that CW later determined that some of the supplements and/or pills that CW sold were counterfeit.

10. CW advised that defendant OTTOMBRINO operated several storefront business, including PRICE RITE, and that defendant OTTOMBRINO also operated an online business, selling, among other things, counterfeit Extenze.

11. CW told law enforcement that defendant OTTOMBRINO supplied CW with the inauthentic products, including a product labeled “Extenze,” that purported to be manufactured by the Victim Company (“counterfeit Extenze”).

12. CW explained to law enforcement that in addition to supplying counterfeit Extenze to CW, defendant OTTOMBRINO also supplied counterfeit Extenze through defendant OTTOMBRINO’s online businesses and through PRICE RITE.

13. CW advised law enforcement that on several occasions between in or around 2012 and in or around 2013, CW visited a warehouse defendant OTTOMBRINO operated in Manalapan, New Jersey, to pick up counterfeit Extenze. During those visits, CW observed numerous boxes of counterfeit Extenze bearing labels resembling the authentic labels for authentic Extenze. CW also observed that the boxes of counterfeit Extenze were stored inside of

¹ CW was the target of criminal investigation involving CW’s involvement in the sale misbranded goods. CW has agreed to cooperate in the investigation into defendant OTTOMBRINO, and has agreed to plead guilty to offenses arising therefrom. The information provided by CW to date has proven to be reliable and credible, and has been corroborated by independent sources.

boxes that were wrapped in customs tape, and that the tape had what appeared to be Chinese characters written across it.

14. A review of lawfully obtained bank records for PRICE RITE indicate that PRICE RITE wired approximately \$680,064 to Chinese entities and individuals between in or around 2011 and in or around 2013.

15. On or about January 11, 2017, under law enforcement supervision, CW met with defendant OTTOMBRINO at SOCIALITE's East Brunswick location. During the meeting, CW paid approximately \$650 to defendant OTTOMBRINO, who, in turn, provided CW with 100 boxes of counterfeit Extenze. The entire transaction between CW and defendant OTTOMBRINO was captured on a concealed audio and video recording device.

16. On or about February 22, 2017, under law enforcement supervision, CW met with defendant OTTOMBRINO at SOCIALITE's East Brunswick location. During the meeting, CW paid approximately \$650 to defendant OTTOMBRINO, who, in turn, provided CW with 100 boxes of counterfeit Extenze. The entire transaction between CW and defendant OTTOMBRINO was captured on a concealed audio and video recording device.

17. On or about August 11, 2017, an undercover Agent ("UCA") met with defendant OTTOMBRINO to purchase approximately \$4,300 worth of goods, including counterfeit Extenze. During the meeting, defendant OTTOMBRINO told UCA that "every pill [he] sell[s] has Viagra in it No matter what it says, it has Viagra in it." Defendant OTTOMBRINO further indicated that some of the products he was selling to UCA were from China and that his supplier put "Viagra" in the counterfeit Extenze. Moreover, during the meeting, UCA paid approximately \$4,300 to defendant OTTOMBRINO, who, in turn, provided UCA 400 boxes of counterfeit Extenze and 10 boxes of a product labeled "SWAG."

18. The FDA sent to the Forensic Chemistry Centre (an FDA-Office of Criminal Investigations Laboratory) samples of the products that defendant OTTOMBRINO sold to UCA and CW from each of the controlled purchases of counterfeit Extenze on January 11, 2017, March 30, 2017 and August 11, 2017, respectively for analysis. The results of the lab tests revealed that each of the samples contained sildenafil, the active pharmaceutical ingredient in Viagra®.

19. Victim Company reviewed photographs of the products that defendant OTTOMBRINO sold to UCA and CW from each of the controlled purchases of counterfeit Extenze on January 11, 2017, March 30, 2017 and August 11, 2017, respectively. Victim Company confirmed that the products

that were sold during the controlled purchases set forth above, do not bear the genuine mark for Extenze. Victim Company has advised in their product labeling that genuine Extenze does not contain sildenafil.

20. Law enforcement performed a side-by-side comparison between the genuine Extenze and the counterfeit Extenze purchased on the dates set forth above, and determined that the labels on the counterfeit Extenze were substantially indistinguishable from the genuine mark associated with Extenze®. The label on the counterfeit Extenze sold to UC and CW did not identify that the product contained sildenafil.

21. During the course of the investigation into defendant OTTOMBRINO, law enforcement determined that defendant OTTOMBRINO used an e-mail address that was registered in his name to communicate with his counterfeit Extenze supplier in China. The contents of this e-mail address were obtained pursuant to a search warrant. A review of these e-mails revealed that from at least 2014 through 2017, defendant OTTOMBRINO (1) instructed his supplier in China to label the counterfeit Extenze to look like the genuine product and (2) further directed his Chinese suppliers to send the counterfeit Extenze to various addresses in New Jersey.





